

## **REMARKS**

### **I. Status of the Application.**

Claims 1-18 were pending in the Application as of the date of the Office Action. In the Office Action, the Examiner rejected claims 1-18 under 35 U.S.C. § 103(a) as allegedly being obvious over International Application Publication No. WO 97/16977 of inventor Antony Scammell ("Scammell") in view of U.S. Patent No. 5,147,548 to Hies et al. ("Hies"), a "FRENCH ENGLISH ABSTRACT" dated January 11, 2002 ("FE Abstract"), and U.S. Patent No. 6,616,927 to Hodgkinson et al. ("Hodgkinson").

In this Response, Applicant respectfully submits the following remarks, amendments to claims 1 and 4-9, cancellation of claims 10 and 11, and new claims 19-22. Applicant respectfully submits that the following amendments and remarks herein traverse or overcome the Examiner's rejections to the claims of the present Application.

### **II. No New Matter Is Introduced by Way of Amendment.**

Applicant respectfully submits that no new matter has been introduced by way of amending claims 1 and 4-9, cancelling claims 10 and 11, and adding new claims 19-22. Specifically, the amendments to claim 4 were to further clarify the method claimed therein consistent with paragraph [0008] of the Application, and claims 1 and 9 were amended to include the same or substantially similar language. Claims 5-8 were amended to reword the claims in view of one or more method steps recited in independent claim 4. New claims 19 and 20 are consistent with paragraph [0008] of the Application and the Application generally regarding how the claimed sterile highly filtered colostrum is prepared. New claims 21 and 22 are consistent with the subject matter of claim 17 and the general concept of injecting colostrum as referenced

within the Application. Applicant respectfully submits that the aforementioned amendments are supported by the originally filed Application and do not add new matter. Accordingly, Applicant respectfully requests that the amendments be entered and that the Application proceed to allowance for the reasons provided herein.

**III. The Rejections of Claims 1-18 Under 35 U.S.C. § 103(a) as Allegedly Being Obvious in View of the Cited Art are Overcome and Should be Withdrawn.**

Applicant respectfully submits that the rejections of claims 1-18 under 35 U.S.C. § 103(a) are overcome and should be withdrawn because neither Scammell, Hies, FE Abstract, nor Hodgkinson, either alone or in combination with one another, disclose all of the limitations of currently amended independent claims 1, 4, and 9. As required under *Graham v. John Deere Co.*, the first steps in determining obviousness is to determine the scope and content of the prior art and ascertain the differences between the prior art and the claims at issue. 383 U.S. 1, 17-18 (1966). "In determining (such) differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02.

Applicant's claim 4, as currently amended and shown in "clean" form, currently reads as follows:

- "4. (Currently amended) A method of preparing sterile highly filtered colostrum, the method comprising the steps of:  
filtering colostrum to remove large components while retaining antibodies;  
lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated; and  
sterilizing the colostrum at the lower temperature."

Independent claims 1 and 9 have also been amended to claim a colostrum made using the process claimed in claim 4. Claims 2, 3, 5-8, and 10-22 are all either directly or indirectly dependent from independent claims 1, 4, or 9.

Scammell

Scammell teaches the preparation of a liquid colostrum product whereby the process includes "subjecting colostrum to centrifugation to substantially reduce the microbial content thereof." Scammell, page 2, lines 3-6. This process, including "bacteria-removing centrifugation," which merely reduces bacterial content, and does not sterilize the product. Scammell, page 4, lines 4-11. Furthermore, the centrifugation is "[p]referably ... conducted at a temperature of approximately 50°C to approximately 64°C," which represents heating the colostrum product during centrifugation. Scammell, page 3, lines 12-13. Scammell does generally reference an embodiment whereby the colostrum is "sterile filtered," but (a) provides no description as to how that process is effectively performed, and (b) states that the sterile filtration "[p]referably ... takes place after the casein removal." Scammell, page 4, lines 8-9. Casein removal, as referenced within Scammell, is performed "in a preferred embodiment ... by precipitation," with no mention as to what "precipitation" means. Scammell, page 3, lines 31-32.

FE Abstract

FE Abstract make reference to a "[n]utritional complement for infants and adults of soya milk and colostrum," whereby the product is "preferably prepared in gel form, packed as single doses in a flexible bag or syringe." FE Abstract, Equivalent Abstract Text (2). Applicant respectfully submits that at most, FE Abstract is only pertinent to the present Application as potentially relating to a product of the present Application that contains colostrum which is

packed in a gel form in single doses in a flexible bag or syringe, and is not relevant as to any method of preparing sterile highly filtered colostrum, a method of providing an animal protection from disease, or of a composition comprising sterile bovine colostrum that has been highly filtered that is claimed or described in the present Application.

#### Hies

Hies teaches a sterile filtered colostrum solution that is prepared by heating colostrum to 37°C, separating a lipid fraction therefrom using centrifugation, adjusting the pH to 3.0 with hydrochloric acid, and then filtering the resulting product. Hies, column 3, lines 17-34. Applicant respectfully submits that no other example provided within Hies discloses a filtered colostrum product that has not been heated, centrifuged, and acidified using hydrochloric acid.

#### Hodgkinson

Hodgkinson discloses parental injection of a substance into a mammary gland to produce IgA in milk. Hodgkinson, column 2, lines 1-44. Specifically, Hodgkinson references an immunization protocol for *obtaining* colostrum and transition milk from an animal (column 2, lines 27-30), whereby various colostrum samples were obtained for testing post immunization (column 12, lines 2-6). Applicant respectfully submits that Hodgkinson clearly relates to immunization to potentially have an effect on the colostrum produced by the immunized subject, and not the preparation of a sterile highly filtered colostrum and uses thereof in accordance with the present Application.

Claims 1-18, as Currently Amended, are Patentable Over the Cited Art

Applicant respectfully submits that currently amended independent claims 1, 4, and 9, and all claims dependent therefrom, are patentable over the cited art as neither Scammell, FE Abstract, Hies, nor Hodgkinson, either alone or in view of one another, claim a colostrum composition prepared as claimed in the present Application. Specifically, neither Scammell, FE Abstract, Hies, nor Hodgkinson teach, disclose, or suggest a method of preparing a sterile highly filtered colostrum including the steps of "lowering the temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated" and "sterilizing the colostrum at the lower temperature" as claimed in independent claims 1, 4, and 9.

As referenced above, Scammell and Hies disclose methods whereby the colostrums are either heated from 50°C to 64°C or heated to 37°C, respectively. To the contrary, currently amended claims 1, 4, and 9 claim a colostrum that is prepared by "lowering the temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated," which, as referenced within paragraph [0008] of the Application and in new claim 19, is performed to minimize denaturation. Furthermore, each of the methods of Scammell and Hies include centrifugation steps, which are required by both Scammell and Hies and are not used within the present Application. In addition, and regarding Scammell, the preferred method of Scammell involves removing casein by precipitation, which is also not part of the claimed or disclosed methods of the present application. Hies, aside from the heating and centrifugation steps, also includes a step of acidifying the colostrum using hydrochloric acid to lower the pH to 3.0, which is not part of any claimed or disclosed method of the present application.

Hodgkinson, as noted above, is not applicable to the present inquiry as it makes reference to a prenatal injection of a substance into a mammary gland to facilitate the internal generation of colostrum. Hodgkinson and FE Abstract relate to injection/immunization, and Applicant respectfully submits that any claim of the present Application, as currently amended or otherwise presented herein, only claims a reference to injection by way of a dependent claim, noting that independent claims 1, 4, and 9, as currently amended, do not claim injection.

Accordingly, and as referenced above, neither Scammell, FE Abstract, Hies, nor Hodgkinson, either alone or in combination with one another, teaches, discloses, or suggests a sterile colostrum as claimed in independent claims 1, 4, and 9. Specifically, neither Scammell, FE Abstract, Hies, nor Hodgkinson, either alone or in combination with one another, teaches, discloses, or suggests a colostrum prepared by "lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated" and by "sterilizing the colostrum at the lower temperature" as claimed in amended claims 1, 4, and 9. At least for this reason, Applicant respectfully submits that the rejection of claims 1, 4, and 9 under 35 U.S.C. § 103(a), and all claims dependent thereon as discussed below, is overcome and should be withdrawn in view of the amendments made to claims 1, 4, and 9

The Rejections of Claims 2, 3, 5-8, and 10-18 are Moot and Should be Withdrawn.

Applicant respectfully submits that the rejections of claims 2, 3, 5-8, and 10-18 under 35 U.S.C. § 103(a) in view of Scammell, FE Abstract, Hies, nor Hodgkinson are all now moot and should be withdrawn because each of these claims either (a) have been canceled, or (b) either directly or ultimately depends from non-obvious independent claims 1, 4, or 9. "If an independent claim is not obvious under 35 U.S.C. § 103, then any claim depending therefrom is

not obvious." MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1382, 1385 (C.C.P.A. 1970)). As claims 10 and 11 have been cancelled, and as claims 2, 3, 5-8, and 12-18 either directly or ultimately depend from nonobvious claims 1, 4, or 9, the rejections of claims 2, 3, 5-8, and 12-18 under 35 U.S.C. § 103(a) are moot and should be withdrawn.

**IV. Petition for an Extension of Time to Submit the Present Response.**

Applicant respectfully petitions for an extension of time of three (3) months, under 37 C.F.R. § 1.136(a), thereby extending the deadline for response, pursuant to 37 C.F.R. §§ 1.7(a) & 1.136(a), to April 6, 2010. Applicant shall authorize payment for this extension in the amount of \$555.00 (small entity) via credit card at the time of electronically filing the present Response.

**CONCLUSION**

For all of the foregoing reasons, it is respectfully submitted that claims 1-9 and 12-22, as currently amended or presented herein, are allowable claims and that Applicant has made a patentable contribution to the art. Favorable reconsideration and allowance of this Application is therefore respectfully requested.

In the event the Applicant has inadvertently overlooked the need for payment of an additional fee, Applicant conditionally petitions therefor, and authorizes any deficiency to be charged to deposit account 09-0007. When doing so, please reference docket number P00902-US-01 (28813.0002). Should the Examiner have any questions regarding the present Response, it is respectfully requested that the Examiner call the undersigned to discuss the same prior to the issuance of a subsequent office action.

Respectfully submitted,

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